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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.		
Typed or Printed Name	Donna Maccedo	
Signature	<i>DM Maccedo</i>	Date 12/10/02

<b>DECLARATION UNDER 37 C.F.R. § 1.132</b>  Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Attorney Docket Confirmation No.	CALD-006 4890
	First Named Inventor	Galer et al.
	Application Number	09/775,592
	Filing Date	January 5, 2001
	Group Art Unit	1614
	Examiner Name	Cook, R.
	Title	Methods for Treating Indomethacin Responsive Headaches

Sir:

I, Lawrence C. Newman, M.D., am a co-inventor of the above referenced application. Enclosed is a copy of my Curriculum Vitae which demonstrates that I am qualified to speak on the level of one of skill in the art.

I hereby declare the following:

Prior to my work in this area as embodied in the present application and claims, it was my expectation, which is the same as with what those of skill in the art would expect, that a topical formulation of indomethacin would not be able to supply **therapeutically effective levels of indomethacin** to be able to successfully treat indomethacin-responsive headaches. As such, prior to my work in this area, the **methods** of treating indomethacin-responsive headaches involved only oral and rectal administration of indomethacin, because it was believed that only oral and rectal formulations (not topical formulations) could supply sufficient levels of indomethacin to treat indomethacin-responsive headaches. Thus at that time, there was an extremely low expectation of success that a topical formulation of indomethacin could supply a

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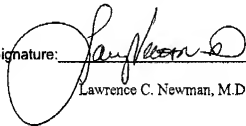
therapeutically effective amount of indomethacin to successfully treat indomethacin-responsive headaches.

The present application and claims are based on our discovery of the unexpected result that a topical formulation of indomethacin provides a therapeutically effective method of treating indomethacin-responsive headaches.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 12/9/02

Signature: \_\_\_\_\_

A handwritten signature in black ink, appearing to read "Lawrence C. Newman", is written over a horizontal line.

Lawrence C. Newman, M.D.

Encl.

\* C.V. of Lawrence C. Newman, M.D.

## **CURRICULUM VITAE**

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### **DATE OF BIRTH:**

January 10, 1958

### **EDUCATION:**

1979	Clark University, Worcester, Massachusetts	B.A.
1983	Universidad Autonoma de Guadalajara, Guadalajara, Jalisco, Mexico	M.D.

### **POST-GRADUATE EDUCATION:**

1984-1985	Fifth Pathway, Elmhurst Hospital Center, Elmhurst, New York
1985-1986	Resident, Department of Internal Medicine, Elmhurst Hospital Center Elmhurst, New York
1986-1989	Resident and Chief Resident, Neurology, Albert Einstein College of Medicine Bronx, New York
1989-1990	Headache Fellow, Headache Unit, Montefiore Medical Center, Bronx, New York

### **PROFESSIONAL EMPLOYMENT**

1988-1996	Staff Neurologist and Research Associate, Headache Unit
1989-1991	Assistant Attending Physician, Montefiore Medical Center, Bronx, New York
1989-1991	Assistant Attending Physician, Bronx Municipal Hospital Center, Bronx, New York
1989-1992	Assistant Attending Physician, Hospital of the Albert Einstein College of Medicine, Bronx, New York
1989-1992	Instructor of Neurology, Albert Einstein College of Medicine, Bronx, New York York
1989-1992	Neurology Consultant, Teaching Nursing Home Study, Albert Einstein College of Medicine, Bronx, New York

**PROFESSIONAL EMPLOYMENT (continued):**

1990-1992	Deputy Director, Neurology, Montefiore Medical Center, Bronx, New York
1990-1996	Co-Director, Montefiore Manhattan Headache Unit, New York, New York
1991-1999	Assistant Professor of Neurology, Albert Einstein College of Medicine, Bronx, New York
1999-	Associate Clinical Professor of Neurology, Albert Einstein College of Medicine, Bronx, New York
1991-	Attending physician, Neurology, Montefiore Medical Center, Bronx, New York
1996-1996	Co-Director, Montefiore Headache Unit, Bronx, New York
1996-1998	Director, Montefiore Manhattan Headache Unit, New York, New York
1996-1997	Director, Montefiore Headache Unit, Bronx, New York
1996-	Faculty member, Women's Health Tract, Albert Einstein College of Medicine
1998-	Director, The Headache Institute at St. Luke's-Roosevelt Hospital and Beth Israel Medical Centers, New York, New York
1998-	Attending physician, Department of Neurology, St. Luke's-Roosevelt Hospital Center, New York, New York
1998-	Attending physician, Department of Neurology, Beth Israel Medical Center, New York, New York
1998-	Attending physician, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, New York, New York

**PROFESSIONAL CERTIFICATIONS:**

1994	Board Certified, American Board of Psychiatry and Neurology (Neurology)
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**PROFESSIONAL SOCIETY MEMBERSHIPS:**

American Medical Association  
American Academy of Neurology  
American Association for the Study of Headache  
National Headache Foundation  
International Headache Society

**HONORS AND AWARDS:**

Leo M. Davidoff Award for Excellence in Teaching, Albert Einstein College of Medicine, Bronx, New York  
Best Poster Presentation, Headache World 2000, London UK

**OTHER PROFESSIONAL ACTIVITIES:**

1990-1992	Quality Assurance Committee, Montefiore Medical Center
1992-1995	Ethics Ad Hoc Committee, American Association for the Study of Headache
1992-1994	Abstracts Co-Editor, Headache
1992-1995	Education Committee, American Association for the Study of Headache
1996-	Education Committee, American Academy of Neurology
1996-	Course Co-Director, American Association for the Study of Headache

Lawrence C, M.D.

2000- Patient Education Committee, Roosevelt Hospital Center, New York, NY  
2000- Course Director, Headache in Adults, American Academy of Neurology  
2000- Editor, Migraine Section, Current Pain and Headache Reports

#### CONSULTANT/REVIEWER:

1991 Ad Hoc Reviewer, Neurology  
1992 Ad Hoc Reviewer, Cephalalgia  
1993 Ad Hoc Reviewer, Headache  
2001 Ad Hoc Reviewer, Journal of Anesthesiology  
2001 Ad Hoc Reviewer, National Institute of Health

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2. Solomon S, Lipton RB, Newman LC. Nuchal features of cluster headaches. Headache 1990; 30:347-349.
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4. Galer BS, Lipton RB, Newman LC, Solomon S. Myocardial ischemia related to ergot alkaloids: A case report and literature review. Headache 1991; 31:446-450.
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8. Newman LC, Lipton RB, Solomon S. Hemicrania continua: Attacks may alternate sides. Headache 1992; 32:237-238.
9. Solomon S, Lipton RB, Newman LC. Clinical features of chronic daily headache. Headache 1992; 32:325-329.

10. Solomon S, Lipton RB, Newman LC. Evaluation of the criteria for the diagnosis of chronic tension-type headache. Cephalalgia 1992; 12:365-368.
11. Newman LC, Lipton RB, Solomon S. Episodic paroxysmal hemicrania: three new cases and a literature review. Headache 1993; 33:195-197.
12. Newman LC, Lipton RB, Solomon S. Hemicrania continua: 10 new cases and a review of the literature. Neurology 1994; 44:2111-2114.
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14. Lipton RB, Lowenkoff T, Bajwa ZH, Leckie RS, Newman LC. Cardiac Cephalalgia: a malignant form of exertional headache. Neurology, 1997; 49:813-816.
15. Lipton RB, Mazer C, Newman LC, Solomon S. Sumatriptan relieves migraine like headaches associated with carbon monoxide exposure. Headache 1997; 37:392-395.
16. Newman LC, Lipton RB, Lay CL, Solomon S. An open-label pilot study of oral Sumatriptan in the intermittent prophylaxis of menstrually-associated migraines. Neurology, 1998; 51:307-309.
17. Newman LC, Steiner DS. Treatment of common headaches. What to do when it's not a migraine. Women's Primary Care, 1998; 1:753-762
18. Lay CL, Newman LC, Post-traumatic hemicrania continua. Headache, 1999;39:275-279
19. Lay CL, Newman LC. Menstrual Migraine: Approaches to Management CNS Drugs. 1999; 12:189-195
20. Solomon S, Newman LC. Chronic Daily bilateral headache responsive to indomethacin. Headache, 1999; 39:754-757
21. Lay CL, Newman LC. Identifying and treating hormonal migraine. Women's Health in Primary Care, 2000; 3:27-35
22. Mascellino AM, Lay CL, Newman LC. Stabbing headache as the presenting manifestation of intracranial meningioma: a report of two patients. Headache, 2001; 41:599-601
23. Newman LC, Manix IK, Landy S, et al. Naratriptan as short-term prophylaxis of menstrually associated migraine: a randomized, double-blind, placebo-controlled study. Headache, 2001; 41:- 248-256

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**B. MONOGRAPHS:**

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2. Newman LC. (Editor). Avoiding common pitfalls in the diagnosis and treatment of migraine headaches. CME Audiotape Program, Annenburg Center, 1996.
3. Newman LC. (Editor). Pitfalls in managing your migraine patients. CME Audiotape Program, Medical College of Virginia, 1998.
4. Newman LC (Editor). How to Select Optimal Acute Migraine Therapy: The Neurologists Approach. Audiotape Program, 1999.
5. Newman LC, Lay CL, (Eds.) Menstruation-Associated Migraine. CME Program, Meniscus Educational Institute 1999

**C. REVIEW ARTICLES AND BOOK CHAPTERS:**

1. Solomon S, Lipton RB, Newman LC. Prophylactic therapy for cluster headache. J Neuropharmacology 1991; 14:116-130.
2. Solomon S, Lipton RB, Newman LC. Differential diagnosis of headache. Hospital Medicine 1991; 27(10):51-61.
3. Sands GH, Newman L, Lipton RB. Cough, exertion and other miscellaneous headaches. In S Diamond (Ed) Medical Clinics of North America 1991; 75(3):722-748.
4. Newman LC, Lipton RB, Solomon S. The hypnic headache syndrome. In: F Clifford Rose (Ed), 1991 New Advances In Migraine Research, Smith Gordon.
5. Solomon S, Lipton RB, Newman LC. Migraine: clinical features and diagnosis. Comprehensive Therapy. 1992;18:24-27.
6. Newman LC, Lipton RB, Solomon S. Taking a headache history. In: CD Tollison and RS Kunkel (Eds.) Headache: Diagnosis and Treatment. Williams and Wilkins, 1993; pp.23-30.
7. Solomon S, Lipton RB, Newman LC. Tension-type headaches: Clinical symptomatology and differential diagnosis. In: CD Tollison and RS Kunkel

8. (Eds) Headache: Diagnosis and Treatment. Williams and Wilkins, 1993; pp.123-128.
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10. Lipton RB, Pfeiffer D, Newman LC, Solomon S. Headache in the elderly. J. of Pain and Symptom Management, 1993; 8:87-97.
10. Lipton RB, Newman LC, Solomon S. Over-the-counter medication and treatment of migraine. (Editorial) Headache. 1994;34:547-548.
11. Newman LC, Lipton RB. Prophylactic drug treatment of migraine. Seminars in Headache Management, 1996; 1(2):10-14.
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22. Newman LC, Lipton RB. Ergotamine tartrate. In Spence PS, Schaumberg HH Experimental and Clinical Neurotoxicology, In Oxford University Press, New York pp. 535-537, 2000.
23. Newman LC Effective management of ice pick pains, SUNCT, and episodic and chronic paroxysmal hemicrania. Current Pain Headache Rep. 2001;5:292-299;
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27. Newman LC, Solomon S, Lipton RB. Post-traumatic hemicrania continua. Neurology. 1997; 48: A23. Presented at the 49<sup>th</sup> Annual Meeting of the American Academy of Neurology, April 15, 1997.
28. Newman LC, Lipton RB, Lay LC, Solomon S. An open-label pilot study of oral Sumatriptan in the intermittent prophylaxis of menstrual migraine. Cephalalgia. 1997; 7 (3): 437. Presented at the International Headache Society Meeting, Amsterdam, Holland, June 12, 1997.

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30. Newman LC, Lipton RB, Lay LC, Solomon S. An open-label pilot study of oral sumatriptan in the intermittent prophylaxis of menstrual migraine. Headache 1998 Quarterly. Presented at the Participating Physician's Approach to the Difficult Headache Patient. Palm Springs, California February 20, 1998.
31. Newman LC, Steiner DS, Kazmi MM, Berliner R. Zolmatriptan for the acute treatment of migraine in sumatriptan non-responders: Open-label pilot study. Headache, 1998; Volume 38. Presented at the 40<sup>th</sup> Annual Scientific Meeting of the American Association for the Study of Headache, San Francisco, June 26, 1998.
32. Newman LC, Steiner DS. Divalproex Sodium (Depakote) as migraine prophylaxis in patients with cognitive side effects to prior treatment with antimigraine agents: A retrospective chart review. Headache Quarterly, 1998. Presented at the Practicing Physicians Approach to the Difficult Headache Patient, Orlando, Florida, June 1998.
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35. Solomon S, Newman LC. Unusual indomethacin responsive headaches. Cephalalgia 1998; 18:411.
36. Newman LC. A pilot study of oral sumatriptan as intermittent prophylaxis of menstruation-related migraine. (letter). Neurology 1999; 52:1301-1302.
37. Newman LC, Lay CL, O'Connor KA, Russell M. Lack of Cross-Reactivity of Sumatriptan in patients allergic to Sulfonamides: A Retrospective chart review. Headache 1999; 39: 372.
38. Newman LC, Mannix LK, Landy SH. Naratriptan as prophylaxis for menstrually associated migraine: A randomized double blind, placebo controlled study. Neurology 2000; 54 (7 Suppl 3): A14. Presented at the 52<sup>nd</sup> Annual meeting of the American Academy of Neurology, San Diego, CA May 2000.

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**E. INVITED LECTURES:**

1. The Pharmacologic Therapies of Migraine Headache. The New Jersey Pharmaceutical Association, Cranford, New Jersey. January 20, 1993.
2. Current Concepts in the Diagnosis and Treatment of Headache. The New Jersey Pharmaceutical Association, Runnemede, New Jersey. January 21, 1993.
3. Migraine: Epidemiology, Pathophysiology, Diagnosis and Treatment. Presented at The Eight Annual Meeting of The Tampa General Hospital Pharmaceutical Committee, Tampa, Florida. January 30, 1993.
4. Headache Overview. The Arnold and Marie Schwartz College of Pharmacy, Queens, New York. May 2, 1993.
5. The Pharmacists Role in the Treatment of Migraine. The Long Island Society of Hospital Pharmacists, Westbury, New York. June 17, 1993.
6. Update on Migraine. Northern New Jersey Society of Hospital Pharmacists, Tenfly, New Jersey. September 23, 1993.
7. Advances In The Treatment of Migraine. Middlesex County Pharmaceutical Association, Denville, New Jersey. October 7, 1993.
8. The Pharmacists Role In the Treatment of Headache. Morris-Sussex Pharmacy Association, Denville, New Jersey. October7, 1993.
9. Migraine: Diagnosis and Treatment. Indian Medical Association, Potomac, Maryland. October 23, 1993.
10. Update on Migraine Therapy. Van Buren County Medical Society, South Haven Community Hospital, South Haven, Michigan. October 30, 1993.
11. The Pharmacist Role in the Management of Headache. Rutgers University, Piscaraway, New Jersey. January 21, 1994.
12. Migraine: Epidemiology, Pathophysiology, Diagnosis and Treatment. The Society for Women's Physicians, Short Hills, New Jersey. April 12, 1994.
13. Epidemiology of Migraine. Presented at the Sixth Annual Congress of Managed Health Care, Washington, DC. April 13, 1994.

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14. The relationship between Headache and Sleep. American Association for the Study of Headache, Scottsdale AZ. November 1997.
15. The relationship between Headache and Sleep. American Association for the Study of Headache, Scottsdale AZ. November 1998.
16. Headaches of Short Duration. American Association for the study of Headache. Scottsdale AZ, November 1999.
17. Evaluation of headaches: the Neurologist Approach. Diamond Headache Meeting, Palm Springs CA, 1999.
18. Headaches of Short Duration. American Academy of Neurology, San Diego CA, 2000.
19. Neurologic Cross-Fire. American Academy of Neurology, San Diego CA. 2000.
20. The Trigeminal Autonomic Cephalalgias. American Headache Society, Scottsdale AZ, 2000.
21. In patient treatment Strategies. American Headache society, Scottsdale AZ, 2000.
22. Chronic Daily and Tension-type Headache. Diamond Headache Meeting. Palm Springs CA, 2000.
23. Migraine Co-Morbidity. American Headache Society, Miami, FL, 2001.
24. Headache of Short duration. American Headache Society, Miami, Florida, 2001.
25. Headache of Short Duration. American Headache Society, Scottsdale AZ, 2001.
26. In-patient treatment Strategies. American Headache Society, Scottsdale AZ, 2001
27. Chronic Daily and Tension-type Headache. Diamond Headache Meeting. Palm Springs CA, 2001.
28. Headache of Short Duration. American Academy of Neurology. Philadelphia PA 2001.

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**LAWRENCE C. NEWMAN, M.D.** – Is an Associate Professor of Neurology at the Albert Einstein College of Medicine and Director of St. Luke's-Roosevelt and Beth Israel Medical Center's Headache Institute. He is a Diplomat of the American Board of Psychiatry and Neurology, being board certified in Neurology. Dr. Newman serves on the Education Committee for the American Association for the Study of Headache and the American Academy of Neurology, and is a member of the American Association for the Study of Headache, the National Headache Foundation, and the International Headache Society. He is an Ad-Hoc reviewer for the journals Headache, Cephalalgia, and Neurology. Dr. Newman was a resident and chief resident in Neurology at the Albert Einstein College of Medicine in the Bronx, New York, and completed a formal Headache Fellowship at the Montefiore Headache Unit. He was the Director of the Montefiore Headache Unit from 1996-1997.

Dr. Newman is on the Advisory Boards and has conducted clinical research for Glaxo Smith Klein, Astra Zeneca, Novartis, Abbott, Pfizer, Bristol Meyers Squibb, and Merck. Dr. Newman is an experienced lecturer who has published extensively on the diagnosis and treatment of unusual headache disorders. He is listed in The Best Doctor's in New York and Who's Who in Science and Medicine.